

SUSTAINED RELEASE BEADLETS CONTAINING STAVUDINE

ABSTRACT

5 Extended dosage forms of stavudine are provided comprising beadlets
formed by extrusion-spheronization and coated with a seal coating. The beadlets
are also coated with a modified release coating such that a hard gelatin capsule
containing such beadlets will provide blood levels of stavudine over
approximately 24 hours. The beadlets are prepared from a dry blend of stavudine,
10 a spheronizing agent, a suitable diluent and a stabilizing amount of magnesium
stearate. The magnesium stearate, in contrast to other similar pharmaceutical
adjuncts, has been found to stabilize stavudine against degradation due to
hydrolysis in the presence of the limited amount of water necessary for the
extrusion-spheronization process. Also included in the scope of the invention are
15 hard gelatin capsules containing, in addition to the stavudine beadlets, similar
beadlets containing other therapeutic agents utilized to treat retroviral infections.

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